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(54) **Hollow coil guide wire apparatus for catheters**

Hohlgewickelter Führungsdraht für einen Katheter

Guide fil creux à spirales pour catheter

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(56) References cited:
EP-A- 0 397 489 EP-A- 0 613 650
EP-A- 0 705 577 US-A- 3 739 770
US-A- 3 973 556 US-A- 4 271 845
US-A- 4 770 188 US-A- 5 125 395

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EP 0 778 038 B1

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Description

BACKGROUND OF THE INVENTION

[0001] This invention relates to catheter systems and more particularly to hollow guide wire apparatus with improved torque and flexure characteristics.

[0002] Catheter guide wires have been used for many years to "lead" or "guide" catheters to desired target locations in the human body's vasculature. The typical guide wire is from about 135 centimeters to 195 centimeters in length, and is made from two primary pieces--a stainless steel solid core wire, and a platinum alloy coil spring. The core wire is tapered on the distal end to increase its flexibility. The coil spring is typically soldered to the core wire at its distal end and at a point where the inside diameter of the coil spring matches the outside diameter of the core wire. Platinum is selected for the coil spring because it provides radiopacity for X-ray viewing during navigation of the guide wire in the body, and it is biocompatible. The coil spring also provides softness for the tip of the guide wire to reduce the likelihood of puncture of the anatomy.

[0003] Navigation through the anatomy is achieved by viewing the guide wire in the body using X-ray fluoroscopy. The guide wire is inserted into a catheter so the guide wire protrudes out the end, and then the wire and catheter are inserted into a vessel or duct and moved therethrough until the guide wire tip reaches a desired vessel or duct branch. The proximal end of the guide wire is then rotated or torqued to point the curved tip into the desired branch and then advanced further. The catheter is advanced over the guide wire to follow or track the wire to the desired location, and provide additional support for the wire. Once the catheter is in place, the guide wire may be withdrawn, depending upon the therapy to be performed. Oftentimes, such as in the case of balloon angioplasty, the guide wire is left in place during the procedure and will be used to exchange catheters.

[0004] As the guide wire is advanced into the anatomy, internal resistance from the typically numerous turns, and surface contact, decreases the ability to advance the guide wire further. This, in turn, may lead to a more difficult and prolonged procedure, or, more seriously, failure to access the desired anatomy and thus a failed procedure. A guide wire with both flexibility and good torque characteristics (torsional stiffness) would, of course, help overcome problems created by the internal resistance.

[0005] Document US 4,770,188 discloses a guide tube assembly for an endoscope comprising a body comprising separable wound sections wound around a porous tube. The wound sections are axially moveable along the porous tube and are drawn together towards the forward end when said porous tube is stretched axially into a configuration to form a stiff body.

[0006] Document EP 0 613 650 A2 discloses a bending device for use in an endoscope or a catheter comprising a pair of limitation members for limiting an axial compression of a coil. The pair of limitation members are arranged along the length of the coil and are mounted respectively on diametrically opposite portions of the coil.

[0007] Documents US 4,271,845 EP 0 397 489 A1, US 3,739,770, US 3,973,556 and US 5,125,395 disclose various coils which may be used in catheters or endoscopes.

[0008] Document EP 0 705 577 A1, discloses an intraluminally implantable stent formed of helically wound wire. The stent has a generally elongated tubular configuration and is readily expandable after implantation in a body vessel. When helically wound into a tube, the waves are longitudinally nested along the longitudinal extent of the stent so as to form a densely compacted wire configuration.

SUMMARY OF THE INVENTION

[0009] It is an object of the invention to provide an improved catheter guide wire apparatus.

[0010] It is also an object of the invention to provide such apparatus which exhibits both torsional stiffness, bending flexibility, and longitudinal strength.

[0011] It is a further object of the invention to provide such apparatus which is simple in design and construction.

[0012] The above and other objects of the invention are realized in a specific illustrative embodiment of a catheter guide wire apparatus which includes the features defined in claim 1.

BRIEF DESCRIPTION OF THE DRAWINGS

[0013] The above and other objects, features and advantages of the invention will become apparent from a consideration of the following detailed description presented in connection with the accompanying drawings in which:

FIG. 1 is a side, fragmented view of one embodiment of a catheter guide wire apparatus made in accordance with the principles of the present invention; FIG. 2 illustrates diagrammatically a method of producing a herringbone coil guide wire apparatus in accordance with the present invention; FIG. 3 illustrates another method of producing a coil guide wire apparatus with bends, in accordance with the present invention; FIG. 4 shows another method of producing either a cylindrical, flat or square strip with serrated edges, for formation into a guide wire coil apparatus in accordance with the present invention; FIGS. 5A and 5B show respectively a side, fragmented view of a coil guide wire apparatus having interlocking ears, and an end view of the apparatus wire; FIG. 6 is a side, fragmented view of a coil strip having interlocking teeth formed in adjacent edges of the strip, in accordance with the present invention;

FIG. 7 illustrates diagrammatically a method of forming a coil from a threaded wire, in accordance with the present invention;

FIG. 8 is a side, fragmented view of a wire coil, showing selected adjacent windings spot welded together, in accordance with the present invention;

FIGS. 9A and 9B show respectively a side, fragmented view of a coil guide wire apparatus which has been canted, and an end view of the coil guide wire; FIG. 10 shows a fragmented side, cross-sectional view, fragmented view of a coil wound from a strip of material having interlocking teeth, in accordance with the present invention.

DETAILED DESCRIPTION

[0014] Referring to FIG. 1, there is shown a side, fragmented view of a catheter guide wire in the form of an elongate coil 4 having a plurality of windings 8. At least some of the windings 8 are formed with adjacent, interlocking bends 12, which inhibit relative rotational movement of adjacent windings. Because of the coil construction, the coil 4 is laterally flexible to enable guiding it around curves and bends in vessels and ducts in the human body. The bends 12 in the windings give the coil 4 torquability so that rotating a proximal end 4a of the coil transmits torque along the length of the coil to a distal end 4b of the coil.

[0015] The distal end 4b of the coil is formed with a curved tip 16, the end of which includes a solder ball 20 or similar blunt tip for the coil. The curved tip 16 allows for guiding the guide wire around curves and bends, as previously discussed. Alternatively, the tip 16 could be made of a shapeable material to initially be straight, so that the user could later curve the tip as desired.

[0016] A central mandrel or core wire 24, which may be tapered and/or curved, is inserted through the center of the coil 4 and soldered or welded (e.g. by laser welding) to at least some of the coils to prevent the coils from separating longitudinally so that torquability can be maintained. The core wire can also serve to control the flexibility of the coil, i.e., stiffen the coil to a greater or lesser extent depending upon the needs of the user. In this manner, the flexibility of the coil can be varied and controlled.

[0017] After or while the guide wire coil 4 is being inserted in a vessel, a catheter would be threaded about the exterior of the coil to be guided to the desired destination location.

[0018] The outside diameter of the coil 4 might illustratively be from .008 inches to .090 inches, with a length of about 1 centimeter to 50 centimeters. Advantageously the coil 4 is made of platinum alloy, nickel-titanium alloy or stainless steel to provide the desired strength, radio-opacity and biocompatibility.

[0019] FIG. 2 illustrates diagrammatically a method of forming bends or a herringbone pattern in a length of wire 34 which is then formed into a coil 38 about a mandrel 44. The bends are formed by moving the wire 34 length-

wise between a pair of rotating wheels 48 formed with teeth 52. The wheels 48 are rotated in the directions indicated so that, to a certain extent, the teeth 52 of the wheels intermesh to form bends in alternating directions as the wire 34 is moved between the wheels. The wire 34 with bends is then wrapped on a mandrel 44 so that the bends of adjacent windings interlock, as indicated, after which the mandrel is removed.

[0020] FIG. 3 diagrammatically shows an alternative method of producing bends 64 in a wire coil 68. Here, a mandrel 72 is threaded both through the coil 68 and through a center opening 76 in a hammer 80. The hammer 80 includes a wedge-shaped tip 84 so that when the hammer is moved along the mandrel 72 into contact with a length of wire 68a which is not yet bent, the hammer forces the length against a previously bent winding to thereby bend the length to conform to the previously formed bends. (The initial winding bent by the hammer 80 would have been forced against an anvil 88, rigidly mounted on the mandrel 72 and bent at the same angle desired for the coil bends 64.) After each winding is bent by the hammer 80, the hammer is withdrawn and the mandrel 72 rotated to position the next length of wire to be bent. After all bends are formed in the wire coil 68, the coil may be held in the coiled position and heat treated to "set" the bends in the coil.

[0021] FIG. 4 shows an alternative example of a coil guide wire formed either from round wire (shown in cross-section at 94), flat wire (shown at 98 in cross-section) or square wire. The wire 102 to be formed into the coil 106 is passed between toothed wheels 110 which impress and form teeth 114 on opposite edges of the wire 102 as shown. The wire 102 is then wound about a mandrel 118 so that the teeth on adjacent edges of the wire intermesh or interlock, as also shown in FIG. 4, to provide the inhibiting mechanism to inhibit relative rotation of adjacent windings of the coil 106. The mandrel 118 may be maintained in the coil 106 as a core wire, after the coil is finished being formed, and soldered or welded to various coils to keep them from separating.

[0022] FIGS. 5A and 5B show respectively a side, fragmented view of a coil guide wire 124, and a front end view. Formed at three spaced-apart locations around each winding is an ear or nipple 128 protruding longitudinally to nest with adjacent ears or nipples, as shown. The nesting of the ears 128 provides the inhibiting mechanism for relative rotation of one winding with respect to adjacent windings to thereby provide for increased torsional stiffness. A core wire 130 is inserted in the hollow of the coil 124 and welded or soldered to various coils as earlier described.

[0023] FIG. 6 shows a side, fragmented view of a coil 144 formed of a strip of material 148 having teeth 152 formed on opposite edges of the strip, at selected locations therealong, so that when the strip is formed into the coil 144, the teeth intermesh or interlock to prevent relative rotation of adjacent windings, while allowing lateral flexibility. A core wire 156 is disposed in the hollow of the

coil 144.

[0024] FIG. 7 illustrates the winding of a threaded wire 164 onto a mandrel 168 to form a coil guide wire 172 in which the threads of adjacent windings intermesh to inhibit relative rotation therebetween. The threads are simple screw threads and may be formed in a conventional manner.

[0025] FIG. 8 shows a side, fragmented view of a coil guide wire 184 having spot welds 188 at selected locations along the coil to join the adjacent coils on either side of the spot welds and thereby prevent relative rotation therebetween. The spot welds 188 are spaced to allow the coil 184 to retain flexibility while also maintaining high torquability. No core wire would be required but may be desired with this embodiment.

[0026] FIGS. 9A and 9B show respectively a side, fragmented view of a canted coil 194, and an end view thereof, with a center support wire 196 welded thereto. "Canting" of the coil transmits rotational force between adjacent windings which, along with the center wire 196, inhibits relative rotation therebetween, as desired.

[0027] FIG. 10 shows a specially formed strip 200 which when formed into a coil provides concentric lips 204 nesting in grooves 206 to prevent lateral or radial movement of adjacent coils relative to one another, and interlocking teeth 208 and gaps 212 to prevent relative rotational sliding of adjacent coils. The lips 204 and teeth 208 and gaps 212 serve to allow torque transmission, while maintaining concentricity of the coils without the need of a center wire.

[0028] In the embodiments of the guide wire discussed above, the guide wires can be made "flow directable" by providing highly flexible distal ends. "Flow directability" means that the distal end of the guide wire tends to "flow" with the blood around curves and bends in a vasculature passageway. To reduce resistance to movement of a guide wire in a vasculature passageway, the surface of the guide wire may be electropolished to increase the smoothness thereof, and additionally, a lubricious coating may be applied to the surface of the guide--such coatings might illustratively include silicon based oil and/or polymer or hydrophilic polymers. Alternatively, a lubricious sleeve made, for example, of a hydrophilic polymer could also be provided for disposal over the guide wire.

[0029] It is to be understood that the above-described arrangements are only illustrative of the application of the principles of the present invention. Numerous modifications and alternative arrangements may be devised by those skilled in the art without departing from the scope of the present invention and the appended claims are intended to cover such modifications and arrangements.

Claims

1. A catheter guiding implement for insertion into vasculature passageways and about which a catheter may be threaded for guidance through the passage-

ways, said implement comprising:

one or more strips of material formed into an elongate coil (4, 68) having a plurality of windings (8) and a central hollow, and first means for inhibiting at least selected adjacent windings from rotating relative to one another, to thereby allow transmission of torque along the coil (4), while also allowing flexure, wherein said strip of material is generally circular in cross-section, and coiled so that adjacent windings (4, 68) are generally in contact, characterized in that said first inhibiting means comprises nesting bends (12, 64) formed in at least selected adjacent windings (8) of the coil (4, 68) to inhibit rotation of the windings (8) relative to one another.

2. A catheter guiding implement as in claim 1 further including second means for inhibiting longitudinal separation of the windings (8).
3. A catheter guiding implement as in claim 1, wherein said material is selected from the group consisting of platinum alloy, nickel-titanium alloy and stainless steel.
4. A catheter guiding implement as in claim 1, wherein said coil (4, 68) is canted generally along its length.
5. A catheter guiding implement as in claim 1 further including a core wire (24) disposed in the hollow of the coil.
6. A catheter guiding implement as in claim 1, wherein said coil (4, 68) has a proximal end (4a) and a distal end (4b), and wherein the distal end is curved.
7. A catheter guiding implement as in claim 6 further comprising a ball (20) disposed in the distal end (4b) of the coil (4, 68) to serve as the leading end of the coil (4, 68).
8. A catheter guiding implement as in claim 1, wherein the outside diameter of the coil (4, 68) is from about 0,203 mm (.008 inches) to 2,29 mm (.090 inches).
9. A catheter guiding implement as in claim 1, wherein the thickness of the strip material ranges from about 0,0254mm (.001 inches) to 0,127 mm (.005 inches).
10. A catheter guiding implement as in claim 1, wherein said second inhibiting means comprises a core wire (20) disposed in the hollow of the coil and joined to at least selected ones of the windings.
11. A catheter guiding implement as in claim 1 further including a lubricious coating disposed over the ex-

terior of the coil (4, 68).

12. A catheter guiding implement as in claim 1 further including a lubricious sleeve disposed about the exterior of the coil (4, 68).

Patentansprüche

1. Katheter-Führungsvorrichtung zum Einführen in Gefäßkanäle, auf die ein Katheter zum Führen durch die Kanäle gezogen werden kann, wobei die Vorrichtung umfasst:

einen oder mehrere Streifen aus Material, die zu einer länglichen Wendel (4, 68) mit einer Vielzahl von Wicklungen (8) und einem mittigen Hohlraum geformt sind, und eine erste Einrichtung, die verhindert, dass sich wenigstens ausgewählte aneinander grenzende Wicklungen relativ zueinander drehen, um so die Übertragung von Drehmoment entlang der Wendel (4) zu ermöglichen und gleichzeitig Biegung zu ermöglichen, wobei der Streifen aus Material im Querschnitt im Allgemeinen kreisförmig und so gewendet ist, dass aneinander grenzende Wicklungen (4, 68) im Allgemeinen in Kontakt sind, **dadurch gekennzeichnet, dass** die erste Verhinderungseinrichtung ineinander geschachtelte Knicke (12, 64) umfasst, die in wenigstens ausgewählten aneinander grenzenden Wicklungen (8) der Wendel (4, 68) ausgebildet sind, um Drehung der Wicklungen (8) relativ zueinander zu verhindern.

2. Katheter-Führungsvorrichtung nach Anspruch 1, die des Weiteren eine zweite Einrichtung enthält, die Trennung der Wicklungen (8) in Längsrichtung verhindert.
3. Katheter-Führungsvorrichtung nach Anspruch 1, wobei das Material aus der Gruppe ausgewählt wird, die aus Platinlegierung, Nickel-Titan-Legierung und rostfreiem Stahl besteht.
4. Katheter-Führungsvorrichtung nach Anspruch 1, wobei die Wendel (4, 68) allgemein über ihre Länge abgeschrägt ist.
5. Katheter-Führungsvorrichtung nach Anspruch 1, die des Weiteren einen Kerndraht (24) enthält, der im Hohlraum der Wendel angeordnet ist.
6. Katheter-Führungsvorrichtung nach Anspruch 1, wobei die Wendel (4, 68) ein proximales Ende (4a) und ein distales Ende (4b) hat und das distale Ende gekrümmt ist.

7. Katheter-Führungsvorrichtung nach Anspruch 6, die des Weiteren eine Kugel (20) umfasst, die im distalen Ende (4b) der Wendel (4, 68) angeordnet ist, um als das vordere Ende der Wendel (4, 68) zu dienen.

8. Katheter-Führungsvorrichtung nach Anspruch 1, wobei der Außendurchmesser der Wendel (4, 68) zwischen ungefähr 0,203 mm (0,008 Inch) und 2,29 mm (0,090 Inch) beträgt.

9. Katheter-Führungsvorrichtung nach Anspruch 1, wobei die Dicke des Streifenmaterials von ungefähr 0,0254 mm (0,001 Inch) bis 0,127 mm (0,005 Inch) reicht.

10. Katheter-Führungsvorrichtung nach Anspruch 1, wobei die zweite Verhinderungseinrichtung einen Kerndraht (20) umfasst, der in dem Hohlraum der Wendel angeordnet und mit wenigstens ausgewählten der Wicklungen verbunden ist.

11. Katheter-Führungsvorrichtung nach Anspruch 1, die des Weiteren eine schmierende Beschichtung enthält, die über der Außenseite der Wendel (4, 68) angeordnet ist.

12. Katheter-Führungsvorrichtung nach Anspruch 1, die des Weiteren eine schmierende Buchse enthält, die um die Außenseite der Wendel (4, 68) herum angeordnet ist.

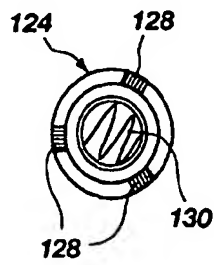
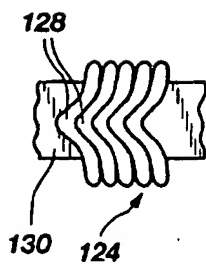
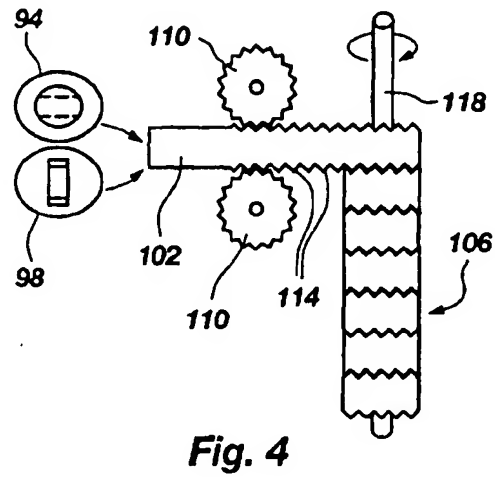
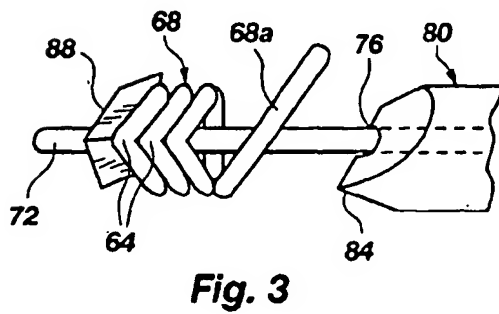
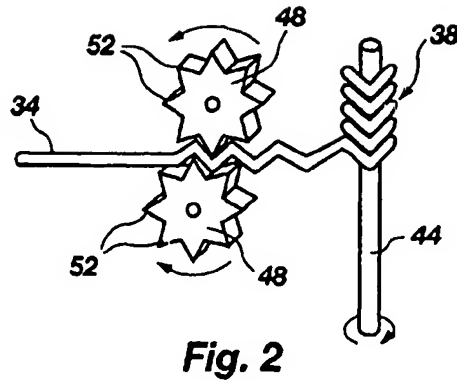
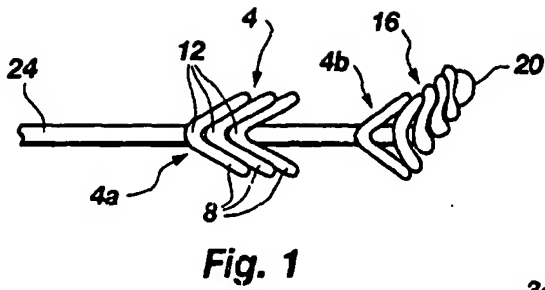
Revendications

1. Appareil de guidage de cathéter pour insertion dans des passages de vaisseau et autour duquel un cathéter peut être vissé pour guidage dans les passages, ledit appareil comprenant :

une ou plusieurs bandes de matériau formées en une bobine allongée (4, 68) ayant une pluralité d'enroulements (8) et un creux central, et un premier moyen pour empêcher au moins des enroulements adjacents sélectionnés de tourner l'un par rapport à l'autre et ainsi pour permettre la transmission d'un torque le long de la bobine (4), tout en permettant aussi une flexion, ladite bande de matériau étant généralement de section transversale circulaire et enroulée de sorte que les enroulements adjacents (4, 68) soient généralement en contact, **caractérisé en ce que** ledit premier moyen pour empêcher comprend des coudes emboîtés (12, 64) formées en au moins des enroulements adjacents sélectionnés (8) de la bobine (4, 68), pour empêcher la rotation des enroulements (8) les uns par rapport aux autres.

2. Appareil de guidage de cathéter selon la revendication 1 incluant en outre un second moyen pour empêcher la séparation longitudinale des enroulements (8). 5
3. Appareil de guidage de cathéter selon la revendication 1, dans lequel ledit matériau est choisi dans le groupe consistant en un alliage de platine, un alliage nickel-titane et l'acier inoxydable. 10
4. Appareil de guidage de cathéter selon la revendication 1, dans lequel ladite bobine (4, 68) est inclinée généralement sur toute sa longueur. 15
5. Appareil de guidage de cathéter selon la revendication 1, incluant en outre une tige d'armature (24) placée dans le creux de la bobine. 20
6. Appareil de guidage de cathéter selon la revendication 1, dans lequel ladite bobine (4, 68) a une extrémité proximale (4a) et une extrémité distale (4b), et dans lequel l'extrémité distale est incurvée. 25
7. Appareil de guidage de cathéter selon la revendication 6 comprenant en outre une balle (20) disposée dans l'extrémité distale (4b) de la bobine (4, 68) pour servir d'extrémité avant de la bobine (4, 68). 30
8. Appareil de guidage de cathéter selon la revendication 1, dans lequel le diamètre externe de la bobine (4, 68) est d'environ 0,203 mm (0,008 pouce) à 2,29 mm (0,090 pouce). 35
9. Appareil de guidage de cathéter selon la revendication 1, dans lequel l'épaisseur du matériau de bande est d'environ 0,0254 mm (0,001 pouce) à 0,127 mm (0,005 pouce). 40
10. Appareil de guidage de cathéter selon la revendication 1, dans lequel ledit second moyen pour empêcher comprend une tige d'armature (20) placée dans le creux de la bobine et reliée à au moins des enroulements sélectionnés. 45
11. Appareil de guidage de cathéter selon la revendication 1, incluant en outre une revêtement lubrifiant disposé sur l'extérieur de la bobine (4, 68). 50
12. Appareil de guidage de cathéter selon la revendication 1, incluant en outre un manchon lubrifiant disposé autour de l'extérieur de la bobine (4, 68). 55

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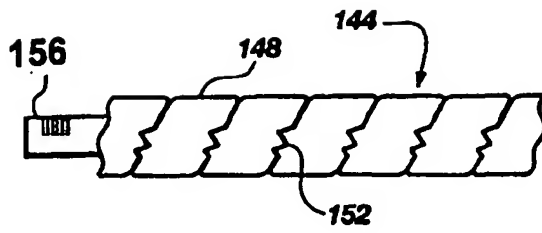


Fig. 6

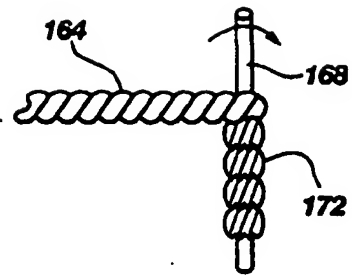


Fig. 7

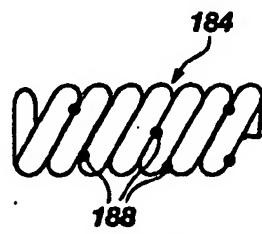


Fig. 8

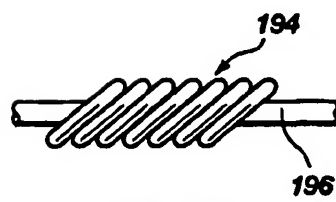


Fig. 9A

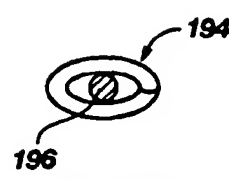


Fig. 9B

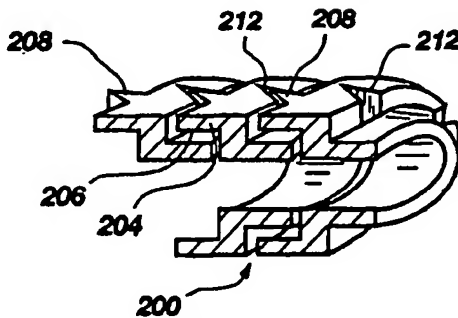


Fig. 10